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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/812,616	03/06/97	BOEHRINGER	H 12046-010500

EXAMINER

HM32/0331

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CHIN. P.	ART UNIT	PAPER NUMBER
		5

1641

DATE MAILED: 03/31/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) _____ 1-20 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) _____ 1-20 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948:
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☒ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-15, drawn to a method of visually quantifying an amount of an analyte in a sample, classified in class 436, subclass 514.
 - II. Claims 16-23, drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514.
 - III. Claims 24-34, drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514.
 - IV. Claims 35-43, drawn to drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514.
 - V. Claims 44-52, drawn to drawn to drawn to a method of determining an amount of an analyte in a sample, classified in class 436, subclass 514.
 - VI. Claims 53-71 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56.
 - VII. Claims 72-81 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56.
 - VIII. Claims 82-95 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56.

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IX. Claims 96-107 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56.

X. Claims 108-119 and 120, drawn to a device and kit for determining an amount of an analyte in a sample, classified in class 422, subclass 56.

2. The inventions are distinct, each from the other because of the following reasons: The inventions in Groups I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Each of the claimed methods of assay in Groups I-V recite the use of different specific binding reagents and different assay devices and thus have different modes of operation.

3. The inventions in Groups VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Each of the claimed assay devices recite different specific binding reagents as well different structural components, i.e. with or without barrier zones, and thus would have different modes of operation. 4. The inventions of Groups I-V and Groups VI-X are related as process and

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apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case each of the claimed apparatus can be used to practice another and materially different process such as affinity chromatography.

4. Because these inventions are distinct for the reasons given above and the search required for any one of Groups I-X is not required for any of the other inventions in the group, restriction for examination purposes as indicated is proper.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

chin/cc
March 29, 1998

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 / 641